

# Exhibit 53

*United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.*

Civil Action No. 07-10248-PBS

Exhibit to the August 28, 2009 Declaration of James J. Fauci In Opposition To  
Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc.  
Local Rule 56.1 Statement of Undisputed Material Facts  
in Support of Their Motion For Summary Judgment

NO. GV3-03079

THE STATE OF TEXAS ) IN THE DISTRICT COURT  
 )  
 ex rel. )  
 VEN-A-CARE OF THE )  
 FLORIDA KEYS, INC., )  
 Plaintiff(s), )  
 )  
 vs. ) TRAVIS COUNTY, TEXAS  
 )  
 ROXANE LABORATORIES, INC., )  
 BOEHRINGER INGELHEIM )  
 PHARMACEUTICALS, INC., BEN )  
 VENUE LABORATORIES, INC., )  
 and BOEHRINGER INGELHEIM )  
 CORPORATION, )  
 Defendant(s). ) 201ST JUDICIAL DISTRICT

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ORAL AND VIDEOTAPED DEPOSITION OF

SHELDON BERKLE

JANUARY 27TH, 2005

VOLUME 1 OF

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ORAL AND VIDEOTAPED DEPOSITION OF SHELDON BERKLE,

produced as a witness at the instance of the  
 Plaintiff(s), and duly sworn, was taken in the  
 above-styled and numbered cause on the 27th of January,  
 2005, from 9:01 a.m. to 5:15 p.m., before CAROLYN J.  
 FORD, Registered Professional Reporter and Notary  
 Public, State of Florida at Large, reported by machine  
 shorthand at the Doubletree Guest Suites, 12200 Tamiami  
 Trail North, Naples, Florida, pursuant to the Texas  
 Rules of Civil Procedure and the provisions attached  
 previously.

A P P E A R A N C E S

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ALSO PRESENT:

EDWARD MILLER, ESQ.  
Assistant General Counsel  
Chief Compliance Officer  
Boehringer Ingelheim Pharmaceuticals, Inc.  
  
Jana Dobin, Videographer

1 A Yes.

2 Q And then you said, I'll look at it for the  
3 recommended pricing for BIPI. You were talking about  
4 Boehringer Ingelheim Pharmaceutical, Inc., which primarily  
5 manufactures branded products?

6 A Yes.

7 Q Who was going to look at Roxane's branded  
8 products?

9 A Again, that would be the senior executive within  
10 the Roxane organization. And at that time it would have  
11 been Jerry Wojta and then ultimately Werner Gerstenberg as  
12 CEO and head of BIC.

13 Q So in November of 1996, the German executives  
14 were looking, reviewing all product pricing for both the  
15 brand side and the generic side of the Boehringer U.S.  
16 operations?

17 A Again, I can only talk for the branded.  
18 Certainly for the branded side, I don't know the details  
19 that they would have got involved in with the generics.

20 Q Well, why would you have put out this information  
21 saying that one of their points, number nine, that you're  
22 giving everybody a heads up on is they want to review and  
23 confirm all product pricing long-term. And you're telling  
24 Ed to review this for Roxane. Doesn't -- doesn't that  
25 tell you that they want to look at the generic prices as

1 well as the brand prices?

2 A Again, I can't interpret, you know, what the  
3 parent company wanted. I would have been conveying a  
4 message.

5 Q Well, Ed Tupa, can you please tell us what -- he  
6 was the guy responsible for the generic side; right?

7 A Yes.

8 Q So why would you be bringing Ed into this picture  
9 giving him a specific job telling him in connection with a  
10 review and confirmation of all -- of all product pricing  
11 long-term if you didn't think the Germans wanted to look  
12 at generic pricing?

13 A Again, I don't know what they wanted to look at  
14 or not look -- wanted or did not want to look at. Ed  
15 would have discussed this with Mr. Wojta and they would  
16 have had whatever appropriate discussions with the parent  
17 company.

18 Q Then you go on. You say (as read): The timeline  
19 for development of these numbers will be very short and I  
20 would recommend that you start looking at this  
21 immediately.

22 A Right.

23 Q (As read): I will confirm the required dates by  
24 Monday, the latest. This is a top priority. And you put  
25 that in all caps.

1 A Uh-huh.

2 Q Did you ordinarily send memos around saying "I  
3 want to see it Monday at the latest and this is a top  
4 priority" in all caps. Was that common?

5 A I would not say it's common. I think it probably  
6 relayed the message I received from the parent companies  
7 saying they have some timeline that they want to look at  
8 -- look at everything.

9 Q Is it -- then you were trying to convey some  
10 sense of urgency?

11 MR. McCONNICO: Objection; form.

12 A Again, you know, I only see what you see and it  
13 would appear that there was some timeline urgency here.

14 Q [By Mr. Breen] Now, if we go back to the first  
15 page and we -- we move up the e-mail chain here to  
16 November 25, 1996, at 1:13 p.m. Do you see this memo from  
17 Herman -- from Herman Dick?

18 A Uh-huh.

19 Q He works with Roxane; right?

20 A I -- I assume on the signature on the top that he  
21 did. I don't even recall him to be honest with you.

22 Q And you see that it's a memo to Ed -- or e-mail  
23 to Ed saying (as read): Judy Waterer and I changed the  
24 budgeted units for ipratropium MDI to reflect a October  
25 1st, 1997 launch.

1 A Uh-huh.

2 Q And then they go on --

3 MR. McCONNICO: Shelly, try to say yes or no when  
4 you respond because --

5 A Yes.

6 MR. McCONNICO: -- it's difficult for the  
7 reporter.

8 A Yes.

9 Q [By Mr. Breen] Then they go on to provide the  
10 information that you told them they were going to have to  
11 provide for the ipratropium MDI?

12 A Again, I don't think I told them specifically  
13 what to do. This, again, is an informational e-mail.

14 Q So when you were saying I will -- all right. And  
15 you're -- you're copied on here; do you see that?

16 A Yes, I do.

17 Q Why would they have copied you if you had  
18 absolutely nothing to do with ipratropium bromide MDI?

19 A Again, there was a dotted-line responsibility  
20 that I had strategically for the organization. I believe  
21 I also previously mentioned to you for ipratropium, this  
22 was a unique case in that it was a generic version of a  
23 brand Atrovent that was marketed by BI Pharmaceuticals.  
24 And, therefore, there was an information exchange between  
25 the two organizations.

1 you had access to a computer; correct?

2 A Correct.

3 Q And I'm sure you know how to use the internet --

4 A Yes.

5 Q -- correct? Do you recall any instance where you  
6 ever attempted to log on to any State of Texas official  
7 web site to check any State of Texas law?

8 A No.

9 Q Do you know whether or not a person under your  
10 supervision could have if they wanted to go on to a web  
11 site and found out what the law of Texas was with respect  
12 to the reporting of drug prices to the vendor drug  
13 program?

14 A Again, I'm not aware whether someone did it or  
15 didn't do it. Certainly if it was pertinent to their job,  
16 then they had the, you know, ability to make the decision  
17 to tap into that sort of web site should it be available.

18 Q Okay. And -- but my question was really more  
19 specific than that. I just want to know did you know  
20 whether or not that service, that ability was even there  
21 and available for someone to check if they wanted to?

22 A No.

23 Q Who under your direct chain of command would have  
24 had the responsibility to know and understand and comply  
25 with Texas law concerning the reporting of drug prices in



1 your direct chain of command?

2 A That would have been under Mr. Ciarelli's  
3 responsibility.

4 Q All right. And with respect to the Roxane people  
5 that had the dotted-line responsibility of reporting to  
6 you, who with Roxane would have had the ultimate  
7 responsibility to be sure that Roxane employees complied  
8 with the laws of Texas concerning the reporting of drug  
9 prices to the Texas vendor or drug program?

10 A Again Mr. Ciarelli had responsibility for both  
11 the BIPI and Roxane products.

12 Q Okay. So -- and I don't want to be too folksy,  
13 but maybe this would be helpful. I know that you've heard  
14 of President Harry Truman.

15 A Absolutely.

16 Q Okay. And Harry Truman, I didn't meet him, but  
17 I've always heard that he had a sign on his desk that says  
18 "The buck stops here." You heard of that story too?

19 A Sure.

20 Q Which means he was ultimately responsible. Do  
21 you understand what the meaning of "the buck stops here"  
22 is?

23 A General terms.

24 Q Okay. With respect to -- first of all with  
25 respect to BIPI, where did the buck stop? On whose desk

1 did the buck stop with respect to understanding Texas law  
2 and complying with Texas law about reporting drug prices  
3 in your direct chain of command?

4 A That would be within Mr. Ciarelli's group.

5 Q And the same question for Roxane, where -- on  
6 whose desk did the buck stop with respect to knowing and  
7 complying with Texas law and reporting drug prices?

8 A Mr. Ciarelli.

9 Q Now, do you know where Mr. Ciarelli is today?

10 A He works within the Boehringer organization in  
11 Ridgefield, Connecticut.

12 Q Okay. And in your mind and according -- do I  
13 understand your testimony to be, that the buck stops with  
14 Mr. Ciarelli and that nobody above that, not you, not Mr.  
15 Gerstenberg, nobody else above that has any duty or  
16 responsibility whatsoever with respect to knowing Texas  
17 law and complying with it concerning reporting of drug  
18 prices?

19 A I think, again, having direct line responsibility  
20 for Mr. Ciarelli, Mr. Gerstenberg having been my boss,  
21 again, it depends on how you interpret "the buck stops  
22 here." Again, we did not -- we were a large organization.  
23 We had thousands of transactions occurring at any one  
24 point in time. You know, thousands of employee -- a  
25 couple thousand employees reporting to me. It was -- I

1 was not involved in every bit of information or decision  
2 that was made throughout the corporation. It would be an  
3 impossibility.

4 Q Okay. And I understand that and believe me I  
5 don't want to quarrel or quibble.

6 A Yeah.

7 Q We talked about buck stopping. You said that  
8 buck stopped with Mr. Ciarelli. My question now is: Is  
9 it your position -- and if it is that's fine, but if it's  
10 not, tell me -- is it your position that there was  
11 absolutely no duty or responsibility above the level of  
12 Mr. Ciarelli within the BI group of companies to see to it  
13 that the laws of Texas concerning price reporting were  
14 followed and obeyed and understood?

15 A I would say I would have some responsibility for  
16 that.

17 Q All right. And what degree of responsibility  
18 would you have had?

19 A I would, again, ensure that people within my  
20 organization, within the organization together with the  
21 assistance of legal department, communicate in general  
22 terms that we had certain compliance responsibility to  
23 adhere to regulations, laws throughout the United States.

24 Q Is Mr. Ciarelli a lawyer?

25 A No, he is not.

1 MR. McCONNICO: It's this one. That's it.

2 Q [By Mr. Breen] Okay.

3 MR. McCONNICO: It has the press thing on the  
4 bottom, that Wall Street Journal article.

5 THE WITNESS: It's not in here.

6 MR. McCONNICO: They steal them sometimes.

7 MR. BREEN: Could you hand him that one?

8 MR. McCONNICO: Sure. I got all kind of notes on  
9 it.

10 MR. BREEN: Just ignore --

11 MR. McCONNICO: Can't read my writing anyway.

12 MR. BREEN: -- the notes.

13 Q [By Mr. Breen] But -- and I assume you've never  
14 seen this before today --

15 A Correct.

16 Q -- that you recall anyway? Now -- now, but Jim  
17 Rowenhorst he report -- he worked under Gregg Ciarelli;  
18 right?

19 A He either worked under Gregg Ciarelli or there  
20 was a -- sort of a state marketing group that reported to  
21 Mike -- Mike Leonetti so may have been some time frame  
22 differences.

23 Q But these -- these guys both work for BIP U.S.  
24 which is Boehringer Ingelheim Pharmaceuticals so there  
25 is --

1 A Correct.

2 Q -- there's no doubt they were under your direct  
3 chain of command?

4 A Yes.

5 Q There's no -- there are dotted lines and straight  
6 lines and hard lines, they're under you?

7 A Yes.

8 Q And they're talking about Combivent unit dose  
9 vial and that was -- that was your baby?

10 A Correct.

11 Q Okay. So we -- we don't have any issues about  
12 the people involved or the drug involved not being under  
13 you on your watch?

14 A Correct.

15 Q Okay. Now, look at this newspaper article that  
16 Mr. Rowenhorst is attaching to his e-mail. It's Medicare  
17 Plans Major Overhaul Target Massive Overpayments by Laurie  
18 McGinley and David Cloud of the Wall Street Journal; do  
19 you see that?

20 A Yes, I do.

21 Q And if you go to the second page, the first full  
22 paragraph it says (as read): State and federal officials  
23 believe that some drug companies are reporting  
24 artificially inflated AWP's to industry guides that are  
25 used for government reimbursement purposes. The companies